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The National Cancer Institute

Contracting Process

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
Public Health Service
National Institutes of Health

The National Cancer Institute

Contracting Process

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FOREWORD

The purpose of this document is to provide:

- an historical accounting of the contract mechanism within the Public Health Service and the National Cancer Institute
- a description of the differences between the contract and grant as they are used in the research environment of NCI
- a description of the many activities associated with the three major stages of contracting - preaward, award, and postaward
- a brief description of several recent audits of the NCI contracting process and some changes that have been made as a result of these audits.

This is a reference document for general purpose use and therefore does not replace nor should it be used in lieu of other official publications, applicable regulations and executive orders relating to contracting or acquisition.

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I. INTRODUCTION

The National Cancer Institute Act of 1937 created the National Cancer Institute and designated grants-in-aid as the primary mechanism for the funding of work outside the Federal Government. This act also introduced Federal funding for training and for the establishment of fellows. These activities remained small until after World War II.

Near the end of World War II, Dr. Vannevar Bush--and others associated with the Office of Scientific Research and Development--decided that wartime experience had demonstrated the value of strong Government funding of research and development activities and recommended that it should be continued in peacetime. The accomplishments of the Manhattan Project and the development of antimalarial drugs were cited as justification for such Government programs.

In addition, there were a number of important scientific projects under way when the war ended, and it seemed unwise to discontinue them. It was decided, therefore, that existing Government organizations would take over the administration of these projects. The Office of Naval Research assumed responsibility for many of the projects in the physical sciences, and the NIH and the PHS for those in the biomedical field.

Because the Navy had for many years used contracts for funding research, the physical sciences projects initiated during the war and afterward were funded by contracts. NIH and PHS, on the other hand, drawing upon their legislative authorities, used grants to fund biomedical research outside the Federal Government.

In 1955, Congress authorized the establishment of the Cancer Chemotherapy National Service Center (CCNSC), envisioning a directed and highly integrated multidisciplinary drug development effort with preclinical and clinical elements. It was an area in which there was not much interest on the part of academia or industry. Dr. Kenneth M. Endicott agreed to head the program, but because of the extent of the research to be performed, the need to stimulate research, and the need to organize and integrate the research, he won permission to use contracts as a mechanism for funding.

From that point on, contracts have been used by the NCI as a major means of funding research and development efforts, in addition to the more traditional use of contracts to procure animals, materials, construction, etc. The Viral Oncology Program, the Drug Development Program, Bioassay Testing Program and the Immunology Program, among others, have all used contracts extensively to stimulate work in these areas.

In 1962, a decision by NIH Director, James A. Shannon, excluded profitmaking organizations from competition for grants, so that support for these organizations was limited to the contract mechanism. Later in the 1960's, decisions were made that severely curtailed the support of [most] foreign projects through grant mechanisms so that contracts were used to a greater degree in funding meritorious foreign projects.

Recently, NCI has used contracts as the mechanism best suited to stimulate major initiatives, including the Biological Response Modifier Program, chemoprevention, and High LET treatment research. Such efforts require as a major emphasis, procurement of materials and equipment.

In the early 1970's, several reports were issued on the use of contracts in the research and development environment. These invariably resulted in changes in organizations and/or procedures to improve the use of the mechanism. Section VIII of this paper provides a brief synopsis of the most relevant reports.

In the late 1970's, the Inspector General, DHEW, and the General Accounting Office criticized certain aspects of NCI contract activities, primarily contract administration. These reports have been the catalyst for many NCI initiatives to improve the process. The Inspector General is in the final stages of his followup review.

It should be noted that in this paper, the descriptions of the characteristics of contracts, the basis for selecting the contract as the instrument of support and the review and administrative procedures associated with the contract depict the current form of the contract as it has evolved over a period of 25 years of use to best satisfy the particular requirements of the department and NIH.

Whereas in many other Federal agencies, the contract has been the primary funding mechanism used to support the full spectrum of activities from basic research to the purchase of supplies, the NCI has utilized two mechanisms to fund its various program activities: the grant and the contract. These mechanisms have been used primarily to support or conduct extramural activities, but in some cases are used for technical support or provision of resources to the intramural programs. With the passage of the Federal Grant and Cooperative Agreement Act of 1977, the use of a third funding instrument, the Cooperative Agreement, was authorized and the circumstances under which all three mechanisms were to be employed by all Federal agencies were formerly defined. In the following sections, characteristics of each of these mechanisms will be discussed separately, including definitions, types and uses, and the review procedures associated with each mechanism.

II. THE GRANT

A. Definition - The grant is a mechanism for providing funding assistance for conducting a variety of activities including research, education, training, demonstrations, and conferences. The private sector is the initiator of the concept and the approach.

Although the degree of Government involvement varies with the type of grant, a general characteristic of the grant mechanism is that the funding agency exercises minimum control over the execution of the activity, viz., operation of the Peer Review System by the Division of Research Grants (DRG) and assurance of compliance with administrative and fiscal policies. Therefore, the private sector grantee is accorded a great measure of freedom and bears the greatest responsibility for the success or failure of the project.

B. Types and Uses - As of October 1979 there were nearly 100 types of grants, all with carefully specified uses. Some could be used only by single agencies, e.g., P 40 Animal Resource Grant Program, Division of Research Resources (DRR); D 16 Grants for Start-up Assistance, Health Resources Administration (HRA), etc. The types of grants awarded by NCI (identified by activity code) are described below.

1. Research Project Grant (RO1): These grants are given to support a discrete, specified, circumscribed project of basic research to be performed by the investigator in an area representing his specific interest and ability. This is usually called a traditional research project. These grants are also used to support proposals solicited through Cancer Research Emphasis Grant (CREG) and Request for Applications (RFA) mechanisms.*

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*The RFA is a technique used to stimulate or discern investigator interest in certain scientific areas. The division that plans to fund grants in a specific scientific field in support of specific initiatives must set aside a portion of its controllable funds that will be used to fund work in the area, should enough high quality applications be approved. Grants are awarded in priority order. However, if the set-aside funds are not enough to award all high quality grants, the remaining grants are not necessarily funded (i.e., they do not go into the NCI grants "pool"). When grants that were initially funded in response to an RFA are up for renewal, they compete for funds with all other grants submitted to NCI. The RFA is supplanting the CREG, a mechanism used only by NCI, which had essentially the same objective.

2. Scientific Evaluation Grants (R09): These grants provide the chairman of an initial review group (study section) funds for operation of the review group.

3. Clinical Cooperative Research Grants (R10): These grants are awarded to support prospective research activities utilizing patient volunteers to assess the effect and value of various treatment modalities. Because the clinical resources necessary for the conduct of a major clinical trial are often not available at a single institution, a cooperative study is initiated which involves investigators in a number of institutions following a common protocol. The Cooperative Group Program is a component of the Division of Cancer Treatment (DCT). DCT personnel are responsible for monitoring and coordinating the grant-supported clinical trials, reviewing the treatment protocols, and analyzing the data therefrom. Beginning in Fiscal Year 1982 this program will be supported by the Cooperative Agreement mechanism.

4. Conference Grants (R13): These grants are awarded to support national or international meetings, conferences, and workshops that are of value in promoting the goals of the national cancer effort.

5. Cancer Control and Rehabilitation Grants (R18): Cancer Control and Rehabilitation Grants support rapid and effective application of cancer research findings in prevention; detection, diagnosis, and pretreatment evaluation; and rehabilitation and continuing care. The purpose of the program is to identify, field-test, evaluate, demonstrate, and promote the widespread application of available and new methods for reducing the incidence, morbidity, and mortality of cancer.

6. New Investigator Research Grants (R23): These grants support basic and clinical studies so that newly trained investigators can stay active during the early stages of their career.

7. Clinical Cancer Education Grants (R25): These grants are available to schools of medicine, osteopathy, dentistry, and public health, as well as to major affiliated teaching hospitals and specialized cancer institutions, for the purpose of improving and expanding education in the prevention, diagnosis, and treatment of cancer and the rehabilitation of cancer patients.

8. National Organ Site Program Grants (R26): These grants are awarded to support planned programs of integrated laboratory and clinical research, which encompass a full range of investigative activity from basic research to experimental therapy focused on cancers of specific organs. There are four active National Organ Site Projects: Bladder, Large Bowel, Pancreas, and Prostate.

9. Program Project Grants (P01): These grants support a broadly based, multidisciplinary, often long-term research program with a specific major objective or a basic theme. A program project, which generally involves the efforts of several relatively large groups, is directed toward a range of problems having a central research focus, often linking preclinical and clinical research. These projects should constitute a system of research activities and projects directed toward a well-defined research program goal.

10. Exploratory Grants (P20): These grants serve to support planning for new programs, expansion or modification of existing resources and feasibility studies. Exploratory studies may lead to the development of specialized or comprehensive centers.

11. Cancer Center Support Grants (Core) (P30): These core grants provide support for cancer center elements required for the planning, development, evaluation, administration, and maintenance of an active and unified center that consolidates and focuses cancer-related activities in a single administrative and programmatic structure. The grants provide support for a core of professional staff, centralized services and resources, and shared equipment in development projects.

12. Cancer Research Facilities Grants (C06): These grants provide matching Federal funds, up to 50 percent, for construction or major remodeling, to create new cancer research facilities. In addition to basic research laboratories this may include, under certain circumstances, animal facilities and/or limited clinical facilities that are an integral part of an overall cancer research effort. Funds for Cancer Research Facilities Grants are limited to $4 million total cost per grant, and the facilities constructed must be used for cancer research for at least 20 years. These grants may be converted to cooperative agreements in the future.

13. Postdoctoral Individual National Research Service Award (F32): Grants of this type provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

14. National Research Service Awards for Senior Fellows (F33): These awards provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

15. Research Career Development Awards (K04): These are postdoctoral awards designed to promote the professional cancer research careers of individuals who are already scientifically productive and show promise of sustained future development.

16. Research Career Awards (K06): These awards were developed to provide lifetime salaries for researchers who were scientifically productive and showed promise of sustained future development. No new awards have been made since 1964, and only five of these awards are currently supported by NCI.*

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*This type of grant has not been awarded since October 1979. As of September 1980, NCI was funding only one K06 grant.

17. Academic Awards (K07): These grants are designed to stimulate research in education for cancer prevention in schools that do not have such programs and to strengthen and improve these programs in schools that do.

18. Continuing Education Training Grants (T15): These awards assist professional schools and other public and nonprofit institutions to accomplish, expand, or improve programs of extensive continuation, extension, or refresher education dealing with new developments in the science of technology of the profession. This type of grant is applied in developing training programs for veterinary pathologists.

19. National Research Service Award: Institutional Awards (T32): These awards are made competitively to qualified institutions to develop or enhance training opportunities at the predoctoral or postdoctoral level. The applicant must have the staff and facilities for the proposed program. After the award is made, the institution's training program director is responsible for selecting the trainees and for administering the program. Residencies may not be supported by this program. Trainees are subject to serviceand/or payback requirements.

20. NRSA Short-Term Research Training (T35): This is a grant to provide individuals with research training during off-quarters or summer periods to encourage research careers and/or research in areas of national need.

21. Cooperative Agreements (U01): This instrument is used where an assistance relationship will exist between NCI and a recipient in which substantial programmatic involvement is anticipated between NCI and the recipient during performance of the contemplated activity. NCI assists, supports or stimulates, and participates substantially with recipients in conducting projects similar in program intent to those for grants.

All grants are peer reviewed by chartered or ad hoc study sections and those exceeding $35,000 in direct costs are also reviewed by the NCAB. An outline of the review process is provided in Figure 1.

STAGES IN THE GRANT PROCESS

PRE-AWARD
AWARD
POST-AWARD
PROJECT CONCEPTION*
• Investigator Develops Research Proposal and Completes Application for Support
• Application is Submitted to NIH Through Investigator's Institution
INITIAL REVIEW
• For Traditional Research Projects (i.e. R01), DRG Assigns Each Project to an Institute for Potential Funding and to a DRG Initial Review Group (Study Section) for Technical Merit Review
• Projects in Certain Areas of Program (e.g. Centers Support, Program Projects) are Assigned to Special NCI Groups for Review
• Site Visits as Necessary
• Priority Scores Assigned
SECOND REVIEW
• Advisory Boards and Councils Perform Review of All Grant Applications Against Broad Program Needs.
• May Review Individual Projects
• Recommend Approval/ Disapproval for Funding to Institute Director
SELECTION FOR FUNDING
Factors Considered:
• Funding Guidelines for Each Program
• Projected Budgets Based on Expected Allocations
• Program History
• Priority Scores
Notice of Award Sent to Institution and Principal Investigator
ADMINISTRATION
• Annual Progress Report from Investigator
• Approval of Major Changes in Research Direction within Scope of Work
• Approval of Major Changes in Budget

*Although Divisional Boards of Scientific Counselors do not usually review individual grant applications, they are responsible for the review of a Division's total program and the role of grants and contracts in implementation of a Division's program.

Figure I

BEST DOCUMENT AVAILABLE

III. THE COOPERATIVE AGREEMENT (UOI)

The cooperative agreement, like the grant is a mechanism for providing funding assistance for carrying out a variety of activities. However, this instrument rather than the grant should be used when substantial involvement between the funding agency and the recipient is anticipated during performance of the activity. Under a cooperative agreement, a partnership is established between the Government and the private sector. The Government establishes broad guidelines for the research, but leaves decisions on approach or methodology to the recipient. Certain mutually agreed to terms and conditions clearly define and limit the Government's role. However, since the cooperative agreement is considered an assistance-type relationship, the initiative and primary discretionary authority rest with the recipient. Here, support is given for the pursuit of knowledge in a broadly defined field identified by the Government. Thus the Government will not become involved in performing the work to be done, but in accordance with the guidelines thus far established, may play a greater part in managing the project. For example, the relationship in spelling out a substantial degree of involvement may include:

- agency power to define performance procedures and standards and to halt the work if these performance measures are not satisfied

- agency review and approval of the work conducted in one phase of a project before work on a subsequent phase can begin

- necessary conditions of agency and recipient collaboration.

The NCI has had no experience with this new instrument and departmental guidance is now in the formative stages. However, it can be stated that the review process for cooperative agreements will be similar to that used for grants.

The NCI plans to convert at least two types of grants to cooperative agreements: the R10, Clinical Cooperative Group Grant; and the C06, the Cancer Research Facilities Grant.

Clinical Cooperative Group studies (supported by grant or contract) serve as good examples of ventures, which by virtue of Government and private sector involvement, qualify readily for support with cooperative agreements.

NCI staff have a substantial programmatic involvement in the conduct of research clinical trials supported both by R10 grants and by contracts. This degree of involvement is necessary for a number of reasons: (1) because resources available are insufficient to permit exploitation of all identified scientific opportunities, resources must be carefully allocated (and resource availability monitored) in order to assure study of the most important questions and to avoid unnecessary duplication of research efforts; (2) to assure that the limited supplies of investigational new drugs are distributed to groups in a manner that will put them to best possible use in advancing the state-of-the-art in cancer treatment; and (3) to facilitate the close monitoring, reporting and control that is required of NCI by the FDA in permitting the institute to sponsor the clinical study of investigational new drugs.

A good example of the type and extent of staff involvement possible in cooperative agreements is the Clinical Cooperative Group Grants, where NCI staff:

- serves as an information resource regarding treatment regimen and clinical trial design
- assists the group in protocol design
- reviews all protocols which are developed by the cooperative groups and approves on a selective basis those involving investigational drugs and more than 100 patients. Investigators may appeal protocol disapprovals to a clinical subcommittee of DCT's BSC which will serve as an appeals panel.
- assists in the design of mechanisms for quality control, data management and analysis
- approves mechanisms established for data management and analysis
- may determine when a protocol should be terminated; such a decision may be appealed
- has option to crossfile or independently file on drugs evaluated under cooperative trials

- advises investigators of specific requirements concerning investigational drug management that the FDA may mandate

- advises investigators of specific needs of the NCI drug development program to obtain clinical information and works as necessary with clinical trials groups to develop the protocols required to obtain such information.

IV. THE CONTRACT (NOI)

A. Definition - A legally defined procurement mechanism whose purpose is the acquisition, generally by purchase, of property or services for the direct benefit or use of the Federal Government. Although the initiative for the concept arises from the Government, the actual scientific use of the instrument and the approach to the work may arise as a consensus of the scientific community. The negotiated contract used by NCI is awarded through a competitive process in which bidders are judged by reviewers on the basis of technical (scientific merit), business and cost factors.

After award the Government has a substantial monitoring involvement in the project which, however, may range from tight control in the case of a resource contract to general surveillance and support in the case of a research contract.

B. Types and Uses

1. The Research Contract - In the research contract, the Government defines the specific area of research (treatment of breast cancer, for example) and may identify general approaches, such as identification of a virus in cancer cells, development of a vaccine, or radiotherapy followed by chemotherapy for the treatment of a disease (see Figure II).

The research contract is often used to stimulate work in an area that has been neglected by the private sector. The development of the research approach is left to the contractor, and his proposal is used by the technical peer review committee to judge his competence and understanding. Here the Government seeks a best effort situation in an endeavor to gain new knowledge. The work to be investigated, and the limits within which the scientific investigation is to be conducted are well defined and are more restricted than the case under a cooperative agreement. Final approval of all aspects rests with the Government during the course of the work.

CHARACTERISTICS OF THE RESEARCH CONTRACT

- Specific Areas of Research and General Approach Sometimes Defined by NCI, Often with Advice from Outside Sources
- Proposal Used by Peer Review Committee to Judge Competence and Understanding
- Protocol Development Accomplished by Contractor
- Approval of Major Aspects of Program Rests with NCI
- Most Often Used to Stimulate Work in a Neglected Area

Figure II

13A

2. The Resource Contract - In this, the Government establishes with greater precision an area of work, provides guidelines as to how the work is to be accomplished, and thus establishes a more specific "deliverable" than is possible with a research contract (see Figure III).

Resource contracts can be used for several purposes and can be classified in terms of the program area supported:

(a) Extramural Support

- Resources - contracts may be designed to produce or acquire drugs, biological materials or test data which are provided to grantees and contractors for use in their research programs. Rarely do these contracts provide for customized services (e.g., testing or screening) designed to respond to specific grantee or contractor requests (FY 1980 obligation - $19,351,000).

- Program Development - contracts may be used to provide services, information and materials that directly support an extramural program. Examples include: the drug development program in which contract support makes possible the synthesis, acquisition, preclinical testing and dose formulation of candidate antitumor agents; the Biological Response Modifier Program in which contract support facilitates the procurement and testing of candidate biological modifiers such as interferon (FY 1980 obligation - $161,464,000).

(b) Intramural Support

Contracts are used also to acquire support for intramural laboratories. These contracts may provide for specific

CHARACTERISTICS OF THE RESOURCE CONTRACT

- Specific Area of Work Identified by NCI with Advice from Boards of Scientific Counselors
- Precise Specifications Provided by NCI and Incorporated in the RFP
- Contractor Required to Follow Specifications
- Most Often Used to Acquire Services and Materials in Support of a Program

Figure III

end items such as animal holding facilities, or they can provide for the performance of certain tests or laboratory procedures which are required to support the in-house research effort (FY 1980 obligation - $21,416,000).

(c) Equipment Development

In some instances the NCI will support the development of equipment required for the conduct of research. This is done only when the equipment is not available commercially or when no private firm is interested in its development either solely or in conjunction with the NCI (FY 1980 obligation - $3,518,000). An example is the development of an ultrasonic imaging system designed to provide high resolution images of the thoracic and upper abdominal anatomy. A system which features an ultrasonic imaging transducer on the tip of an endoscope has been developed. In tests in dogs and human control subjects, the unit has provided clean images of many organs including heart, liver, kidneys, spleen and pancreas.

3. Special Contract Uses

(a) The Task Order Contract - The purpose of the task order contract is to make available several contractors who are able to perform specific activities designated by the Government. This arrangement provides for quick response to a specific requirement, makes accessible a pool of contractors with varied expertise, isolates costs for each project, provides flexibility for funding (funds are committed only as needed) and avoids prolonged contract competition once the master agreements are awarded (FY 1980 obligation - $3,000,000).

(b) The Interagency Agreement - These may be either research or resource contracts. The distinction is that the "contractor" is another Federal agency. The NCI has agreements with the VA, FDA, USDA and several other Federal agencies (FY 1980 obligation - $22,595,000).

(c) The Prime Contract - The scope and/or complexity of some work requires a number of contracts. Here, the Government may select one contractor to be the "prime" with authority to monitor a number of subcontracts in such areas as technical performance, timely delivery, and coordination between the participating contractors. The Government, however, makes all major program decisions and retains the senior management role - which is concerned with one instead of many contracts. As a result of some criticisms of their use and the increased difficulty of obtaining their approval, the number of prime contracts has declined and will probably continue to do so. Currently, NCI has two prime contracts in force: Tracor Jitco Inc. ($21.4 million) for bioassay operations; and Battelle Memorial Institute ($2.2 million) for protocol toxicology studies.

C. Pricing Arrangements - There are a number of pricing arrangements which can be agreed to by the Government and the contractor concerning a variety of business and cost factors which became a part of the binding contract instrument. These arrangements include primarily such factors as: establishing the method of payment and reimbursement to the contractor, the determination of the allowable fee (profit). Currently, the NCI uses four pricing arrangements in its contracting activities. The key features of the arrangements are shown in Figure IV.

PRICING ARRANGEMENTS USED BY NCI

- **Cost Reimbursement**
  - Used with educational and nonprofit institutions when the costs cannot be estimated accurately. Provides for payment of all allowable costs up to a limit specified in the contract during performance.

- **Cost Plus Fixed Fee**
  - A cost reimbursement contract with a fee to be paid for performing the work. The fee is a profit and thus applies to commercial firms. Certain nonprofit institutions also receive a fee but it must be used for institution business and cannot be distributed to shareholders.

- **Cost Plus Award Fee**
  - A Cost Plus Fixed Fee contract which contains an incentive for additional fee. In addition to a small fixed fee, the contractor has the opportunity to earn more fee based upon a Government review panel's evaluation of his performance.

- **Firm Fixed Price**
  - Provides for a firm price to be paid upon acceptance of each deliverable item. The prices are in effect ceilings, and adjustments cannot be made. Used when the precise method of accomplishing the work can be specified and is not subject to improvisation or change as work progresses.

Figure IV

V. SELECTION OF THE MECHANISM OF SUPPORT

Until recently grants and contracts have been available to Federal agencies to establish necessary assistance and procurement relationships with outside organizations. Although the grant has been used to provide assistance and support in a fairly uniform manner, the contract has been employed in much more diverse ways and in some instances has been used by Federal agencies to meet all or most of the full range of agency needs for procurement and assistance.

With the implementation of the Federal Grant and Cooperative Agreement Act of 1977, the cooperative agreement became available as a second assistance mechanism and the characteristics and uses of grants, cooperative agreements and contracts were spelled out very precisely. Although in the absence of much operating experience, the act and OMB's implementing guidelines may permit varying interpretations. However, it is clear that NCI, along with all other Federal agencies, now has two assistance and one procurement mechanism at its disposal. Thus, there is a greater opportunity to select the funding instrument best suited to the characteristics of the work to be supported. Moreover, NCI has plans for the use of the cooperative agreement in the immediate future, e.g., to support cooperative clinical trials.

With the notable exception of CCNSC-sponsored research, the NCI used the grant to support virtually all extramural research until the mid-1960's. These efforts were primarily conducted by universities and nonprofit organizations. From the mid-1960's to the mid-1970's, with the development of large scale national programs and the increased participation in NCI research programs of private industry - which was not eligible for grant support - the contract was used to a greater degree to support extramural research efforts. Also, congressional mandates to quickly supplement several research efforts made the contract an ideal choice because, at that time, it was a very efficient and expeditious way to procure a wide variety of activities - usually requiring less than 6 months for the entire procurement process.

During the last several years, the contract has for a number of reasons been used less and less to support basic research: (1) new regulations which lengthen and

complicate the procurement process (Section VI); (2) criticisms of the administration of several of the steps in the procurement process; (3) questions concerning the quality and importance of the research supported by contract; and (4) NIH emphasis on maintaining a stable level of research grant support (RO1 and PO1).

It is reasonable to believe that use of research grants, submitted as a result of RFA solicitation, and cooperative agreements will provide instruments for research support that will both provide quality work and retain a measure of the precision and specificity in addressing important cancer problems.

Today, the choice of funding instrument rests primarily on the nature of the relationship to be established between the Government and the outside organization: should it be assistance or procurement? For certain types of activities, the contract is the only appropriate mechanism: the procurement of animals, drugs, materials, etc.; the procurement of goods and services (including research) from other Federal agencies (the interagency agreement); and the procurement of goods and services (including research) from private, profitmaking organizations. Figure V shows generally the relationship between the type of work to be performed and the choice of the funding instrument. Figure VI shows the predominant funding instrument based on project type.

Regarding the degree of Government involvement typically associatd with the three funding instruments: the contract requires the most; the cooperative agreement permits variable degrees based on need (see also page III-1); and the grant requires the least. These relationships are depicted in Figure VII. Inasmuch as the Government involvement in the case of contracts is solely monitoring and in the case of cooperative agreement may include both monitoring and programmatic input, the character of the Government involvement in the two instruments is quite different.

TYPICAL CHARACTERISTICS OF GRANTS, COOPERATIVE AGREEMENTS AND CONTRACTS

	GRANT	COOPERATIVE AGREEMENT	CONTRACT
1) Purpose	To Assist, Support or Stimulate Research, Etc.	To Assist, Support or Stimulate Research, Etc.	To Procure a Specified Service or Defined End Product
2) Project Initiator	Investigator	NIH	NIH
3) Detailed Project Definition	Investigator	Investigator (Within NIH Guidelines)	NIH
4) NIH Program Staff Involvement	Little or None	Moderate to Substantial	Substantial

Figure V

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Predominant Funding Instrument Based on Project Type

Project Type \ Mechanism		Grant	Cooperative Agreement*	Contract
Fundamental Research		Typically	(Choice)	
Applied Research		Frequently	(Choice)	Typically
Development				Typically
General Research Support		Always		
Construction	Extramural	Typically	(Choice)	
	Intramural			Always
Materiel (supplies, animals, drugs, etc.)				Always
Multiinstitutional Clinical Trials		Choice	(Choice)	Choice
Technical Support				Always
Training and Education		Typically		

*The NCI does not currently have any cooperative agreements in force. Parenthetical entry is used to indicate project types where this new mechanism could be used in the future.

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Figure VI

RELATIONSHIP OF FUNDING MECHANISM TO GOVERNMENT INVOLVEMENT

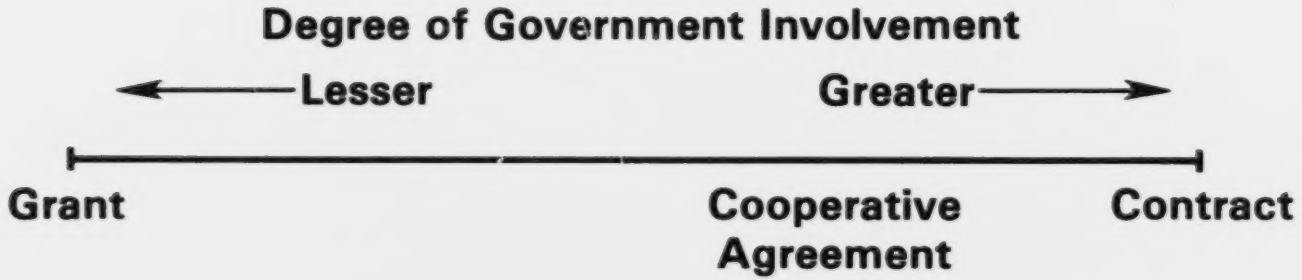

Figure VII

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VI. THE DEVELOPMENT OF A CONTRACT

A. Introduction

The process of awarding contracts at the NCI requires a substantial amount of both staff and outside peer involvement. The review process for contracts involves three essential stages: preaward, award, and post-award. The preaward stage has three parts--planning, solicitation, and evaluation/selection (see Figure VIII). The solicitation part of the pre-award stage and the negotiations conducted in the award stage is handled solely by the NCI staff. Outside peers along with NCI staff are involved in other parts and stages of the process.

This section will describe and define the contract process, including concept review, technical merit review, and NCI staff involvement. The major focus will be on the substantial change that has taken place over time in the review process itself. Also included are the key changes in contracting procedures that have contributed to the current, elongated process.

B. Definitions

1. Concept Review

The first review in the contracting process is a determination of the basic purpose, scope and objectives of the project in relation to the mission of the division. This is commonly referred to as concept review and for the sake of uniformity is conducted by each division's board of scientific counselors. The law requires that the chairman and at least 75 percent of board members be non-Federal employees but in practice membership of these boards is drawn almost entirely from non-Federal sources. Based on a knowledge of the division's mission, programs, objectives, budget and resources, each board brings together the disciplinary expertise, which serves as the counterpart of that found within the division.

STAGES IN THE CONTRACT PROCESS

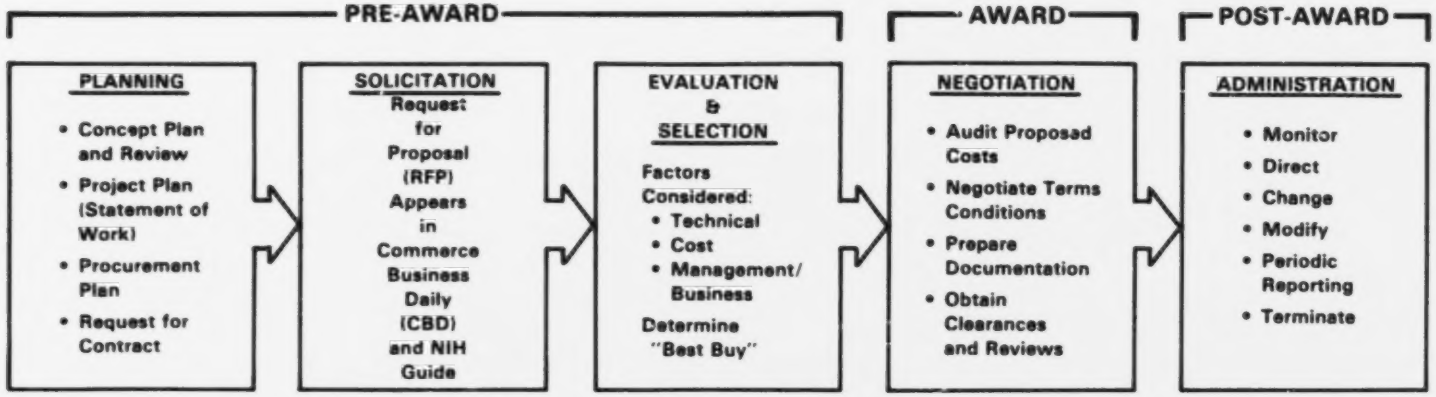

Figure VIII

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Each proposed project which may have first been conceived by advisors or staff is described at a meeting of a board of scientific counselors. In reviewing a project, the board considers the goals of the proposed activity and what technology and other resources are available to achieve these goals, and makes the following recommendations:

a. Whether the project is consistent with the missions and objectives of the division;

b. Whether the purpose, scope, and objectives of the project have scientific merit;

c. Whether the resources to be devoted to the project are enough to accomplish its objectives;

d. Whether the suggested time period is long enough to accomplish these objectives;

e. Whether the project could be supported with a grant or cooperative agreement instead of a contract;

f. Whether the project is properly classified (as a resource/research contract and/or a competitive-/noncompetitive contract);

g. Whether the priority level assigned a project should be high or low, given the total resources and competing activities of the division.

NCI policy requires concept review of all contract projects including resource/support contract projects. Review of concept is required on all new competitive and noncompetitive

contracts, all intra-interagency agreements, and all renewals, including recompetitions of existing contracts and extensions which add $100,000 or more and extend the period of performance for 6 months or more. When projects are planned to encompass multiple contract awards, a single concept review is conducted for the entire project.

2. Technical Merit Review

Research and development proposals, submitted by the private sector in response to an RFP, are evaluated by a peer review committee which must consist of at least 75 percent non-government employees. These committees are under the administrative control of the NCI's Division of Extramural Activities, which is organizationally separate from the initiating division. At NCI, virtually all committees are staffed totally by non-government individuals. Further, these committees are chartered pursuant to the Federal Advisory Committee Act and their meetings are advertised in the Federal Register. (In exceptional circumstances involving single meeting ad hoc reviewers, chartering is not required but meetings are publicly announced.)

The purpose of technical merit review is to get expert advice and consultation on the qualifications of the offeror's staff, the merit of his scientific/technical approach, the sufficiency of staff and institutional experience and the availability of equipment and facilities. Each proposal is reviewed by the peer review committee and the results of its deliberations are documented by an NCI Executive Secretary, who makes the findings of the peer review committee available to the contracting officer and project officer.

In performing its review, the peer review committee evaluates the following:

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a. The contractor's understanding of the scope of the work and the Government's needs;

b. The scientific or technical approach to meet these needs;

c. The realism of the proposed time schedules;

d. The availability of experienced scientific personnel, including their qualifications and professional experience, and the percentage of time they will spend;

e. The adequacy and availability of necessary research, tests, and facilities;

f. The accomplishments, developments, or pertinent ideas of the offeror in the specific branch of science or research involved;

g. The offeror's willingness and ability to devote resources to the proposed work agreement.

Based on the findings and recommendations of the peer review committee, the contracting officer in collaboration with the appropriate program staff, determines with whom the Government will conduct negotiations. This determination generally includes all offerors who have demonstrated the ability to perform the contract project and who are, based upon the scoring and ranking by the peer review committee and the proposed cost, competitive with other offerors. These negotiations consist of discussions of the business/cost proposal and on any ambiguities, deficiencies or weaknesses noted in the proposal by the peer review group. Offerors are given an opportunity to revise their proposals, which are then reviewed by an ad hoc committee of program staff. In some cases, the revised proposals are reviewed by the original peer review committee.

3. Staff Involvement in Pre-Award Review Process

Most of the concepts behind contract development do not originate with NCI staff members; rather they are the result of interaction between staff and members of the scientific community. Concepts may come from several different sources (workshops, seminars, consensus committee recommendations, and ad hoc groups of consultants). In many cases, the concept may result from work which has been completed under a previous contract or grant or from recommendations from the boards of scientific counselors.

Nevertheless, NCI's scientific program management and contracting staffs play major roles in the contracting process. Members of the scientific staff of the sponsoring division have the primary responsibility for preparation of the concept paper, the statement of work, and the evaluation criteria. Their consultation with the senior management staff and contract specialists in the division is critical to the successful and timely execution of the contracting process.

After identifying a new concept, the scientist who will serve as project officer will develop a brief concept paper that will be circulated to staff for review and comment. A recent change in the review process dictates that if enough interest is generated within the division, the concept will be presented to the board of scientific counselors for review and recommendation of approval or disapproval to the Division Director. The project officer describes the merits of the proposed project to the board.

If a concept is recommended by the board for approval, the project officer, consulting with the contract specialist and with other representatives of the division, prepares the statement of work and the evaluation criteria. The documents are then incorporated into a project plan, which is the official request for contract. In a procedure new for most divisions, this document

is presented to the division's senior scientific and management staff for review, comment, and approval. The final version is incorporated by the contracting officer into the Request for Proposal (RFP).

The project officer also attends the technical review of the proposals that are submitted in response to the RFP, and assists the contract specialist in negotiations. At the technical merit review meeting, the project officer, although considered an information resource, is not allowed to make evaluative statements about the proposals. When negotiations are held, the project officer assists the contract specialist in preparing questions for the offerors. He makes certain that all weaknesses, ambiguities, and certain deficiencies noted in the technical merit peer review are provided to the offeror for response. He also evaluates the judgmental direct costs included in the cost proposal, and his comments are provided to the contracting officer and Government cost auditor for consideration in analysis of the business proposal.

C. The Contracting Process - Past and Present

Introduction

Over the past 25 years, the contracting process within DHEW (now HHS) has undergone significant change. Although most of the changes have improved some aspect of the process, each change has also added time to the execution of practically each step in the process. Probably the most important changes promulgated by NCI have resulted in the greater participation of outside scientists and advisors in the review aspects of the procurement process, and in the evaluation of contract performance as a part of overall program planning and budget responsibilities now assumed by the several divisional boards of scientific counselors.

Historically, the many changes in the contract program can be grouped into four time periods: 1956-1970, 1971-1973, 1974-1979, and 1980 to reflect the current process. These changes are highlighted in Figure IX and discussed in more detail below.

1956-1970

The negotiated research contract was first used by NIH in 1956 in conjunction with the Cancer Chemotherapy National Service Center (CCNSC) Program of the NCI.

In subsequent years other NCI program areas, e.g., viral oncology, adopted the contract mechanism to support research and resource development. From the mid-fifties until the early seventies the procedures required to use this mechanism were simple and rapid.

- The entire contracting process was performed almost entirely by NCI staff with limited input by outside consultants.
- Concept review as currently defined did not exist. Project planning, RFP development and determination of relevance, priority, and need were performed almost entirely by NCI staff.
- In competitive procurements, technical merit review and contractor selection were performed by NCI inhouse program committees. Outside advisors participated only at the discretion of program leaders.
- Single source awards to the educational institutions could be made without competition.
- Upon completion of inhouse technical review, a contract could be awarded following negotiations between the contracting officer and the selected offeror.
- The procurement process from planning to award took less than 5 months.

HIGHLIGHTS OF CHANGES IN THE CONTRACT PROCESS: 1956-1980

Time Period	Pre-award		Post-Award Monitoring and Evaluation	Examples of Programs Utilizing Contracts Initiated During Time Period
	Concept Review	Technical Merit Review		
1956-1970	Concept review as currently defined did not exist. Development of proposals for both research and resources contracts and determination of need, relevance, and priority performed by NCI staff.	Technical merit review performed by NCI staff with outside staff involvement at discretion of Division Director—usually on an individual scientist basis.	Primarily NCI staff responsibility with periodic **ad hoc** evaluations of contract performance (usually as part of program review) by Extramural and Intramural peers at option of Division Director	1. Cancer Chemotherapy National Service Center 2. Viral Oncology 3. Chemical Carcinogenesis 4. Breast Cancer Task Force 5. Less Hazardous Cigarette
1971-1973	• Concept review and merit review separate • Outside peer involvement optional • Composition of review groups predominately outside scientists • Research contracts only • Resource contracts still reviewed by NCI staff	• Equivalent of merit review performed by NCI staff for research contracts • Peer merit review at discretion of Division Director • Some chartered review committees established		1. Immunology 2. International Cancer Research Data Bank 3. Cancer Control 4. Surveillance, Epidemiology, End Results (SEER)
1974-1979	• Concept review mandatory as per NIH guidelines • Review committees predominately extramural Scientists • All Divisions appointed BSC* but used differently. DCT/BSC performed concept review of R&D and resource contracts. Other Divisions used intramural review of research and resource contracts	• Mandatory peer review of technical merit of R&D contracts by chartered review committees composed of predominately extramural scientists • Resource contracts reviewed by NCI staff		1. Neutron Generator 2. Nutrition 3. National Toxicology Program 4. Biological Response Modifiers 5. Cancer Centers Patient Data System
1980	• Mandatory concept review by BSC for all Divisions of both research and resource contracts. OD contracts reviewed by subcommittee of the NCAB	• Mandatory peer review of research and resource contracts by chartered committees composed predominately of extramural scientists • Administration of technical merit review of all contracts (Divisions & OD) responsibility of Division of Extramural Activities	Divisional Boards perform evaluations of contract performance as part of their overall review responsibilities. Also for contract renewals over $100,000 and extensions of 6 months or more	– None –

* Board of Scientific Counselors

Figure IX

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- Postaward administation was an NCI staff responsibility. Upon the discretion of program leaders, intramural or non-NIH peers were invited to participate in ad hoc evaluations of contract status and contractor performance. Such evaluations were usually conducted as a part of program reviews.

1971-1973

The early years of the decade of the 1970's saw the introduction of the first of a variety of regulatory and procedural changes that have served along with later changes to radically alter a basically uncomplicated system. Each of these changes has increased the complexity of the procurement (contracting) process and has added to the time required for its completion.

- "Competitive range" negotiations were mandated in 1970 in HEW Procurement Regulations which limit selection of a contractor on the basis of evaluation of initial proposals to very special circumstances. Requires that those proposals deemed to be in the "competitive range" (i.e., those with a reasonable chance for award) be allowed by proposal clarification and correction of certain deficiencies to improve their proposals and submit "best and final offers." The evaluation of these "best and final offers" then becomes the basis for contractor selection. This process adds a minimum of 30 to 45 days to the contracting process.

- In 1972 HEW authorized NIH to decentralize its contracting operations to NCI and several other Institutes. At the same time a centralized Board of Awards was created. This board had to review all NCI contracts over $750,000, a process which added 10 to 15 days to the contracting process for about 25 percent of NCI contracts.

During this period NCI began to involve nongovernment scientists to a modest degree in some phases of the procurement process.

- Concept review, an evolving technique, was not yet a formally articulated function. Division Directors to a variable degree began to exercise their option to involve divisional advisory bodies (composed primarily of non-NIH scientists) in this and other presolicitation phases of the research contracting process (e.g., project planning).

- Some chartered committees were established.

- Technical merit review of research contracts was performed largely by NCI staff although outside committees participated in this activity at the discretion of Division Directors.

- The responsibility for all phases of the procurement of resource contracts was retained by NCI staff.

- Postaward contract administration remained the responsibility of NCI staff.

1974-1979

From the middle 1970's to 1980, the provisions of a number of additional laws, regulations, and procedural changes were put into effect.

- In 1974 amendments to the National Cancer Act required that research and development contract proposals be subject to peer review by groups composed of not less than 75 percent non-Federal employees. In the case of proposals involving innovative and original approaches, a double peer review is required: of concept before RFP development; and of proposals

submitted in response to the RFP. The logistics of organizing and conducting these reviews adds 30 to 60 days to the contracting process.

- Since the late 1970's, great emphasis has been placed on awarding contracts to small businesses including organizations which are socially and economically disadvantaged. Accordingly, every NCI project that is to be contract-supported must be screened to determine if the work can be conducted by small business, minority business, women-owned business, or an organization in a labor surplus area. This screening process can add weeks to the procurement cycle.

- In 1977, HEW implemented a number of initiatives to tighten up contracting procedures in the department. These involved establishment of new clearance, approval, and reporting requirements. These more rigorous requirements can add as much as 60 days to the contracting process.

In March 1979, major changes took place in the area of noncompetitive procurements--those situations where the Government program staff feel that there is a best and uniquely qualified "sole source" for the procurement:

Prior to March 1979

- Each NIH bureau, institute and division (BID) had "signoff" authority for sole source procurements up to $100,000.

- NIH had unlimited "signoff" authority in the dollar levels of sole source procurements.

After March 1979

- BIDs have "signoff" authority for procurements up to $25,000.

- From $25,000 to $100,000, "signoff" is by the NIH Division of Contracts and Grants.

- From $100,000 to $500,000, "signoff" is by the Director, NIH.

- Over $500,000, "signoff" is by the Assistant Secretary for Health.

A variety of other mandatory steps have been added to the procurement process since the middle 1970's. These include preaward clearance of NCI contracts greater than $1,000,000 by the Office of Federal Contract Compliance Programs, Department of Labor, to insure that the contractor has an approved Affirmative Action Plan. In 1979, the Congress passed Public Law 95-507 which requires a plan for subcontracting to small and disadvantaged business as part of all contracts exceeding $500,000.

During this period these requirements along with changes introduced by NCI produced significant changes in the balance of staff/advisor involvement and responsibility in the procurement process.

- All divisions established boards of scientific counselors, but did not uniformly designate their functions.

- Concept review of contracts was mandated by NIH.

- DCT's Board of Scientific Counselors was given the authority for concept review of research and resource contracts. The advisory group of the former Division of Cancer Control and Rehabilitation (now a part of the Division of Resources, Centers and Community Activities) was given similar authority. More recently DCCP's Board of Scientific Counselors has assumed responsibility for concept review of research contracts.

- Except for DCT, NCI staff retained the responsibility of all phases of the procurement of resource contracts. DCT staff retained responsibility for all but the concept review step.

- Technical merit review of R&D contracts by chartered outside peer review committees became mandatory.

- Technical review of resource contracts is conducted by NCI staff.

- With two exceptions, post-award contract administration totally remained the responsibility of NCI staff. DCCR (now part of DRCCA) through the technique of "merit review" of ongoing contracts, accorded outside advisors a measure of responsibility in contract monitoring and evaluation. The Board of Scientific Counselors of DCT, by assuming a responsibility for concept review, took a role in program review and evaluation in which contract performance is a factor.

1980

There are still differences in the divisional handling of planning, evaluation, and postaward administration of contracts. This is, however, a period of transition in which all divisions as well as the OD are to implement mandated methods for all phases of the procurement process. This will bring a much needed and desired uniformity to the NCI contracting process.

- Mandatory concept review of research and resource contracts by the divisional board of scientific counselors and in the case of OD offices by a subcommittee of the National Cancer Advisory Board.

- Mandatory technical merit review of research and development and resource contracts by chartered or ad hoc committees (predominantly non-Federal scientists).

- Technical merit review of all contracts (divisional and Office of the Director) to be administered by the Division of Extramural Activities.

- In the area of postaward administration, divisional boards of scientific counselors: (1) will perform evaluations of contract performance (as a function of program review) and (2) will review performance and concept of proposed contract renewals (extensions adding $100,000 or more and extending the performance period for 6 months or more).

Prior to 1970, the NCI could award a contract in 6 months or less. Due to all the changes described above, it now takes 9 to 12 months starting with concept review. Figure X shows the chronology of the steps involved and their approximate lead times. Because much of the additional time is required for the review process, NCI may be able to bring about some reduction in lead time by improved planning and coordination.

D. NCAB Review of Contracts

There has been considerable discussion of the degree of involvement of the NCAB in the contracting process, and several options for this involvement have been proposed for NCI staff and discussed at meetings of the board. The following motion was passed at the November 1980 meeting of the NCAB which expresses the board's position on this matter.

MOTION:

In order to facilitate interchange between the National Cancer Advisory Board and the boards of scientific counselors of the divisions of the National Cancer Institute and to enhance the capabilities of the NCAB to carry out its mandated responsibility of monitoring programs and recommending policy of the National Cancer Plan to the Director of the NCI, the following recommendations are presented to the Director for formulation beginning in 1981:

(1) Chairpersons of the boards of scientific counselors (BSC) or their designates are invited to attend all meetings of the NCAB and its subcommittees and shall attend the November meeting

STEPS IN THE NCI CONTRACTING PROCESS

Activity	Responsibility	Number of Days: Specific Action	Number of Days: Cumulative
Concept Review	Board of Scientific Counselors		
Project Plan Approval	Research Contracts Branch Section Chief/ Division Director	14	14
CBD/NIH Guide Notice Published	Contract Specialist	14	28
RFP Issued	Contract Specialist/ Contracting Officer	14	42
Proposals Received	Contract Specialist	45	87
Technical Evaluation	Division of Extramural Activities	45	132
Preparation and Distribution of Minutes	Executive Secretary	10	142
Review of Minutes and Revision (if necessary)	Contract Specialist/ Executive Secretary	14	156
Source Evaluation Group Review	Contracting Officer/ Project Officer	10	166
Competitive Range Determination	Contracting Officer	7	173
Written/Oral Discussions	Contracting Officer/ Project Officer	10	183
Receipt of Best and Final	Contract Specialist	14	197
Review of Best and Final	Source Evaluation Group	14	211
Source Selection	Research Contract Branch Section Chief/ Division Director	7	218
Audit of Cost Proposal	Division of Contracts and Grants	30	248
Final Negotiation	Contract Specialist	14	262
Documentation	Contract Specialist	14	276
Review of Files	NIH Board of Awards/ Division of Contracts and Grants	14	290
Contractor Signature	Contractor	7	297
Award	Contracting Officer	5	302

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Figure X

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of the NCAB and participate in the program reviews at that time. At this meeting, each chairperson will report on the year's activities of his/her BSC.

(2) Copies of the minutes of each BSC meeting and those of their subcommittees shall be forwarded to all members of the NCAB as soon as they have been drafted. The activities and policy recommendations of the BSC's should be clearly delineated in such minutes. These will be given the most serious consideration by the NCAB in decisions on policy and program. A standing invitation for members of the NCAB to attend the meetings of the BSC's has been given by the Director.

VII. IMPROVEMENTS IN THE NCI CONTRACTING OPERATIONS

In recent years, the NCI has initiated several major steps to improve its contracting activities - an ongoing process resulting from evaluations conducted by both internal and external groups. Major changes in the review process are described in Chapter VI and additional improvements are described below.

A. Separation of Proposal Review from Program

Before May 1978, the NCI operating divisions were responsible for the peer review of all contract proposals. Although these committees were constituted within the guidelines of the Federal Advisory Committee Act and the Peer Review Regulations, it was determined that because the executive secretaries and the committees were administratively responsible to the Division Director, the strict objectivity of the review process might be questioned.

Therefore, in October 1978, the responsibility for the review of all research and development contract proposals (but not resource contracts) was assigned to the then Division of Cancer Research Resources and Centers. This was part of an Institute-wide reorganization which in part resulted in a new Division of Extramural Activities (DEA) which is now responsible for all proposal reviews. The committees and executive secretaries involved in the process are also assigned to the DEA. This action placed all peer review of technical merit in a division separate from the divisions with direct program responsibilities. It established independence for the peer review groups and resulted in one uniform approach to peer review in contrast to the varying methods used in the past.

B. Changes Within the Research Contracts Branch

NCI has taken steps also to improve the organization and operation of the Research Contracts Branch. Some of the more recent improvements are listed below:

1. Centralization of the Research Contracts Branch Staff

Since its inception, RCB staff members have been located with the program areas they supported. It was thought that this was the most effective way to accomplish the partnership of project officer and contract officer, a partnership essential to the success of the contract process. However, this has caused other problems within RCB. Because the Office of the Chief, RCB, was physically separated from the contract specialists, the chief's ability to provide the level of direction and supervision needed by the staff was hampered, particularly in the area of contract administration. By mid-October 1980, NCI had centralized geographically the entire RCB. This is expected to foster better management of the workload and of the staff, more effective contract administration, and better training of contract specialists.

2. Emphasis on Contract Administration

As a result of the Civil Service Reform Act, managers and executives will be evaluated for merit pay on critical job elements. The Chief, RCB, has advised his section chiefs and team leaders that contract administration will be an important item in performance appraisal. In addition, the chief has established a Contract Administration Review Team which is responsible for auditing the quality of contract administration within RCB. This team is under the direct supervision of the Deputy Chief, RCB, and is led by a senior contract specialist. This first review was completed in August 1980 and within the next 12 to 15 months the performance of each contract specialist within RCB will be reviewed.

The results of the team's findings will be presented to the Chief, RCB, for consideration. It is expected that, where justified, unfavorable reports will be considered in merit pay evaluation.

In addition to contract administration reviews, the Office of the Chief has established a retrieval system for the information related to the reviews of all contracts assigned to each contract specialist in the Branch. As of October 1980 RCB can retrieve comments by the RCB Review and Approval Officer and the NIH Board of Awards for every action over $500,000 for the past 2 years. This information will be available for training and evaluation.

3. Review Procedures

Additional emphasis will be placed on the review and approval of certain contractual documents. In the past, contracting officers have had significant authority in the area of project plans, justifications for noncompetitive procurements, competitive range determinations and source selections. In some cases, the authority delegated to the section level may have led to certain action decisions without consultation with the Office of the Chief. To provide for more effective direction and leadership, effective October 1, 1980, the number of RCB staff with approval authority was reduced, in many cases by as much as one-half.

VIII. EXTERNAL EXAMINATION OF NIH/NCI CONTRACTS

A. Background - The use of contracts in the biomedical research environment has been the subject of many examinations since 1962. The majority of these addressed the use of contracts to obtain research, the management of contracts and grants in biomedical science and the staffing of organizations to enhance the quality of targeted research. Of primary interest are those studies which affect overall policy and operation. The following reports are worth noting:

1. Report to the President on Government Contracting for Research and Development, 1962 (The Bell Report). This study examined general Federal policy regarding the Government's use of the contracts to private institutions and enterprises to obtain research and development work needed for public purposes. The report supported both the mutual benefits of the "partnership" between Government and private institutions and the strengthening of public research and development agencies, so that they could manage extramural activities. The Bell Report also endorsed peer review and nongovernment advice in science programs, even when Government staff are competent to evaluate the scientific aspects.

2. Biomedical Science and its Administration: A Report to the President, 1965 (The Woolridge Committee Report). This report tended to consider contracts and grants interchangeably and recognized that both were research support mechanisms. The committee expressed concern over the scientific quality and propriety of those activities supported by contract. The NCI Cancer Chemotherapy Program and the Collaborative Perinatal Project of the National Institute of Neurological Diseases and Blindness (now the National Institute of Neurological and Communicative Disorders and Stroke) were singled out. It was recommended that the NIH: keep collaborative programs as small as possible; allow "contracting out" for project coordination and analysis; and establish a firm policy that no collaboration program be initiated unless a "strong management team" is established.

3. Report of the Secretary's Advisory Committee on the Management of the NIH Contracts and Grants, 1966, (The Ruina Report). The Ruina Committee was established to study the distinction between grants and contracts, the nature of administrative arrangements necessary to assure proper use of grants and contracts, and the circumstances surrounding current and prior use of contracts at the NIH. The committee assumed that new knowledge stemming from increased basic research efforts would increase the opportunities for realistic programs targeted to the application of knowledge. The committee made several specific recommendations for strengthening the management of targeted research: (1) that grant research be continued and be protected from "encroachment of problems attendant on the increasing need for the NIH to embark upon programs of directed research or development"; (2) that proper staffing policies and practices, organizational structures, and management mechanisms be developed to enhance the quality of targeted research; and (3) that National Advisory Councils--although not responsible for review of individual contracts--should review and comment upon the overall programs of their respective institutes, including targeted research programs. The committee also noted the difficulty of mounting targeted research and development programs by contract in a field of science where the clientele were familiar and comfortable with investigator-initiated activity supported by grants.

4. Review of Research Contracts at the NIH, 1969 (The Sisco Report). The report represents the conclusion of an evaluation of contract management operations at the NIH. The team conducted both an audit of selected contracts and a survey of research contract operations. The study team found that the NIH's contracting practices were in compliance with law and regulation, but the organization of the contract management responsibilities was improper for a program of the diversity, scope, and magnitude of the NIH. As a result of the specific recommendations, authority to negotiate and award contracts was delegated in 1971 to those NIH Institutes with large contract programs.

5. Report of the Ad Hoc Committee to Review the Special Virus Cancer Program, 1973 (Zinder Report). This study was requested by the National Cancer Advisory Board. The report was critical of the quality of peer review and the appearance of conflict of interest on the part of reviewers and program managers. The report recommended a restructuring of the review groups to include more nongovernment scientists and to lessen the influence of the NCI members. In addition, the committee recommended that all contract projects be open to competitive bidding within 3 years. The committee closed with a statement of concern over what it perceived as the "erosion" of the support base of fundamental science.

6. Report of the NIH Program Mechanisms Committee, 1973 (The Cooper Committee Report). This committee was established by the NIH Director, to "review the means and methods used in formulating and administering programs at the NIH." The committee developed its recommendations around the assumption that the "goals of the agency should not be confused with the means for attaining those goals." The committee made seven general recommendations intended to rationalize program planning, development, and review; to encourage development and application of uniform and consistent policies and procedures for program planning and implementation; and to improve communication among the NIH staff and between the NIH and other Government agencies and the scientific community. Rather than change existing mechanisms or their application, the committee's recommendations suggested the development of a rational means for making plans and setting priorities for the application of the mechanisms. These reports focused little attention on the aspects of contract administration and other technical aspects of the contract process such as cost analysis, statements of work, contract monitoring and competition. Such attention came later by various investigative/review offices.

B. Recent Audit Report - During the past 3 years, NCI has been the subject of several reports on contracting activity. These reports dealt with the more technical aspects of contracting. Several of the reports were unfairly critical of NCI operations. In some cases, there were questions about qualifications of the auditors, the methodology employed, the sampling procedures utilized, and the consensus reached. The NIH Director, in a memorandum of October 1978 to the Assistant Secretary for Health, stated: "....(these reports) contain hypotheses and reviewer opinions that have not been subjected to normal post audit dialogue between reviewer and the organization under review. This fact finding and analysis step is critical to establish the validity and reliability of the reviewers' findings and recommendations. It is evident that an auditor or reviewer not required to discuss and explain the basis for his or her findings is given the role of judge, jury and executioner. Unfortunately, this has been the principal mode of operation of the DHEW review teams operating at NIH in recent months." In other cases, NCI and NIH staff agreed with the findings and were able to make, as a result, improvements in the contracting activity.

1. May 1978 Report by the Inspector General (IG) DHEW

The most comprehensive and critical review of the NCI contract program was the May 1978 Inspector General's (IG) Report.

NCI disagreed with many aspects of the report but decided not to respond formally to the draft since NCI and IG staffs were to discuss it at a later date. Indeed in a November 1978 memo the IG noted that efforts to resolve differences in presentation were under way. NCI staff met with staff of the IG in 1979. In an April 1979 memo the Chief, RCB, NCI, stated the purpose of the meeting "...was to give institute impressions of the report and to identify errors. It was agreed that no purpose would be served by reanalyzing the data to resolve factual discrepancies. Moreover, the IG did not wish to review the report item by item for the following reasons: (1) the IG auditors were not procurement experts and thus could not

respond to or perhaps understand NCI philosophic points and (2) the IG's return visit would be designed only to cover recommendations made in the report and would not be another audit." Thus errors made in the report were never corrected and differences in opinion never resolved. The NCI's failure to respond to the report led many in the department and in the scientific community to form inaccurate opinions of the manner in which NCI does business. The NCI staff later regretted that it had not rebutted the report more vigorously. In a memorandum to the Assistant Secretary for Health, dated November 1978, the NIH Director stated: "Because there are substantial areas of disagreement in portions of the Inspector General's Report, we regret our earlier decision to not discuss the report in detail on the merits of various issues. Our failure to discuss the draft report when it was issued early in 1978 may have contributed to a misleading impression about the department that we concur in the validity of the IG Report without qualification, which we do not."

2. June 1980 Report by the General Accounting Office (GAO) on the DCCR Contract Program

This review was conducted by GAO at the request of Congressman David Obey. The request identified several issues which were of interest to the Congressman.

This is the most recent examination of the NCI contract program. The report, which involved almost 6 months of field work and several months of drafting was answered by the NCI and a copy of the response was included in the GAO publication. However, because of the time constraints imposed by Representative Obey, GAO gave the Institute approximately 72 hours to review the draft and to prepare its response.

GAO reviewed a total of five DCCR (now part of DRCCA) contracts. Several GAO conclusions were based on three specific contracts which represent 0.9 percent of DCCR's contracts. In many cases, NCI found the GAO conclusions did not give due consideration to the documentation provided. For example, GAO stated that DCCR's contract review groups identified 52 problems and made 43 recommendations. The auditors could not find any indication that NCI directed the contractors to implement the review recommendations. NCI provided GAO with memoranda from the NCI project officers detailing the corrective and followup actions taken by the Institute. Although NCI's documentation could have been better, the institute had taken adequate steps to correct the problems.

3. 1980 Followup Report by the Inspector General (DHHS)

During 1980, the IG returned to NCI to determine how NCI had responded to recommendations made in its May 1978 Report. The IG draft report was received by NCI in mid-November; the NIH response was forwarded to PHS on November 26. The report shows that NCI has taken many corrective actions, but that further improvements are needed.

C. Suggestions for Improvement

Following is a brief synopsis of specific suggestions made in the 1978 IG Report and the 1980 GAO Report discussed above and corrective actions taken as a result:

1. PreAward Process

The reports suggested that comments made about specific contracts by peer or technical review groups were not used by the project officer and contracting officer in later negotiations, and that weaknesses noted in the peer review process were not always corrected prior to the Institute making a contract award. Actually, this is more a problem of inadequate

documentation by NCI of its actions, than it is of failure to take the actions. The suggestion did result in improvement in documentation of NCI followup actions on specific suggestions. The reports also noted a lack of adequate cost analysis of contracts, and suggested that statements of work were too broad and the requirements contained in them were poorly defined. The cost analysis problems are real, due to inadequate numbers of contract staff at NIH, and lack of lead time in processing contracts. NCI is working to correct these problems through better education of contract specialists and improved procurement planning to allow more time for cost analysis. Comments about work statements were inappropriate to a great degree, primarily because auditors did not understand that in a research and development environment, the RFP is deliberately broad to allow for innovative and unique approaches to a problem.

2. Peer Review

The outside audit reports suggested that occasionally review committees did not reach consensus because some committee members were absent from meetings, and that reviewers were not adequately prepared. This is a rare occurrence, and executive secretaries are continually urged to strive for effective operation of review committees. The reports also suggested that peer reviewers often criticized the quality of proposed efforts. In these cases, however, the committees usually voted to continue the project. In addition review committees sometimes take issue with concepts already approved by a board of scientific counselors, suggesting a need to reinforce the roles of various committees to their memberships.

3. Contract Administration

This is the area of greatest criticism of NCI contracting activity, and the area in which NCI has taken the most corrective actions. The reports made a number of suggestions and comments: (a) contracting officers and project officers should work more closely together; (b) contract monitoring should be more formal and effective; (c) contractors should provide better reports on the amount of time spent on a contract by their personnel; (d) project officers did not always review progress reports; (e) project officers sometimes provided oral approval to contractors without the contracting officer's knowledge; (f) contracting officers sometimes did not take action after learning that reports had been received; and (g) project officers sometimes did not follow-up on their site visit recommendations to contractors.

In order to correct these deficiencies, NCI has taken a number of actions. Training for both project officers and contract specialists has been increased. Before 1978, there was little emphasis on formal project officer training; now all must receive training, and now 57 percent of project officers have completed required training. Project officers, contract officers and principal investigators have been issued a manual on contract administration and a Guide to Principal Investigators to help them with their administrative duties. Project officers are required now to review their programs semiannually and to advise their supervisors and the contracting officer of progress and problems. Finally, the number of contract specialists certified pursuant to DHHS guidelines has risen to 50 percent of those employed, and by next year will reach 75 percent.

4. General Comments

There were three main general comments made in the reports: that NCI should increase the percentage of awards made competitively; that project officers sometimes exert undue influence over contracting officers; and that the percentage of obligations incurred in the fourth quarter of the year is too large. As to the number of competitive awards, NCI believes it has a good record. It is estimated that about 60 percent of NCI contract dollars were awarded competitively in FY 1980. Imprecise and contradictory definitions from DHHS have led to differences in interpreting the NCI record. NCI does not agree that project officers unduly influence contracting officers; however, the NCI Director has reinforced the contracting officer's independence in the contracting process. As to fourth quarter obligations, the implication that contracts issued late in the fiscal year are somehow suspect is unfortunate and inaccurate. All contracts take 9 to 12 months of preliminary work before they can be finalized. In FY 1980, NCI obligated 22 percent of its contracts' budget in the last quarter. This is not excessive.

APPENDIX A

GLOSSARY

Agreement, Supplemental

A modification of an existing contract by the mutual action of the parties to it.

Commerce Business Daily (CBD)

A widely read daily newspaper published by the Department of Commerce of U.S. Government procurement invitations, subcontracting leads, contracts awarded, sales of surplus property and foreign business opportunities.

Concept Review

A determination of the scientific/technical merit of the purpose, scope and objectives of a proposed project. This review applies to all NCI contracts (i.e., research and resource/support) and must be conducted by a panel of non-government peers. In its review, the panel must take into account, from a scientific standpoint, the goals of the proposed activity and the availability of the technology and other resources necessary to achieve them.

Contract

A binding legal instrument which reflects the relationship between the Federal Government and another party, such as a local government or private organization, when the purpose of the instrument is to acquire by purchase, lease, or barter, property or service for the direct benefit or use of the Federal Government. While the Government plays no direct role in the performance of the procurement activity, it has a substantial involvement through monitoring of performance.

Contract, Award Fee

This is a cost-plus-fixed-fee contract that contains an incentive to encourage the contractor to perform better than he otherwise might. In addition to a small fixed fee, the contractor has the opportunity to earn more if the Government judges that he has performed especially well.

Contract, Completion

A completion type contract is one that describes the scope of work to be done as a clearly defined task or job with a definite goal or target expressed and with a specific end product required. This type is used for the development of a product or where a final report of research accomplishing the goal or target is required.

Contract, Cost Plus Fixed Fee

This is a cost reimbursable contract with the addition of a fee to be paid the contractor for performing the work. The fee is the contractor's profit and thus applies to commercial contractors. Certain nonprofit institutions are also paid a fee but it must be reinvested or used for institution business and cannot be distributed as a profit in any form.

Contract, Cost Reimbursement

The type of contract used when the costs of a project cannot be accurately predicted. It provides for paying the contractor all proper costs incurred during performance up to a limit specified in the contract.

Contract, Cost Sharing

A cost sharing contract is one under which the contractor receives no fee (in the case of commercial organizations) and is reimbursed only for an agreed portion of the allowable costs incurred during performance of the contract. The unreimbursed portion of the cost of performance represents the contractor's contribution to what is, in effect, a joint enterprise.

Contract, Fixed Price

The fixed-price contract is an agreement by the contractor to furnish designated supplies or services at a specified price which is not subject to adjustment because of performance costs. This type of contract is best suited for procurements where reasonably definite specifications are available and costs can be predicted with reasonable certainty.

Contract, Level of Effort

Under a level of effort contract, the contractor is obligated to devote a specified level of effort labor hours for a stated period of time. Usually the minimum and maximum number and type of labor hours that the Government is purchasing are specified in the contract.

Contract, Resource

A contract that provides services or materials in support of program. Generally, specifications for these contracts are precisely written and the contractor is required to follow them. The following are examples of resources: routine screening activities, equipment procurement, production and procurement of chemical and biological materials, routine pharmacology and toxicology studies, general Phase I, II, III clinical trials.

Contract, Research

Contracts that are primarily for research as opposed to the acquisition of services and materials in support of research. Such research may be fundamental, applied, or in some cases, developmental. A research contract is generally one in which the contractor must be innovative in the development of work processes, etc. and for which it is generally not possible to develop work specifications. However, the NCI requires a desired end product as part of the overall program mission (which may be in the form of a report).

Contract, Task Order

This is an agreement, usually a cost reimbursement contract, which permits the NCI to issue an order against an existing contract. The basic or master agreement results from a competitive procurement which identifies the specific requirements to be ordered in the future. Currently this type of contract is being

used in the DCT Phase I and II Clinical Trials and the NIEHS Bioassay Training Program. The task order contains its own scope of work and is used by the master contractor to submit a proposal for each task order. Selection for award follows the competitive procurement guidelines.

Contract Administration

The management of all facets of contracts to assure that the contractor's total performance complies with his contractual commitments and to assure that the obligations of the Government are fulfilled.

Contract Negotiator

The individual assigned to negotiate the contract up to, but not including, the point of signature. The contracting officer who signs the contract may also have acted as the contract negotiator.

Contract Specialist

A person who is subject to the general supervision of the contracting officer and who actually carries out most of the procedural steps, as contrasted with the approvals, required to be taken by the contracting officer under applicable regulations.

Contract-Fee for Research Material

At the present time there are several contracts in existence which allow researchers to purchase research material from the contractor at a fixed price. Products are specialized biological materials and other therapeutic substances usually not available elsewhere and would not be available except for the Government's interest. Such materials could include research animals, virus materials, cell cultures, tissue samples, etc. The contractor credits his contract with the amount paid by the researchers for the materials. This amounts to the Government establishing and funding a commercial enterprise although not for the purpose of earning a profit.

Contracting Officer

The Government's authorized agent for dealing with the contractor. This individual has authority to negotiate and award contracts on behalf of the Government and to make changes and amendments to the contract.

Federal Procurement Regulations (FPR)

Regulations which apply to civilian Federal executive agencies to the extent specified in the Federal Property and Administrative Services Act of 1949, as amended, or in other law. These regulations apply to procurements made within and outside the United States.

HHS Procurement Regulations

Regulations, applicable to all the Department's procurement activities, which implement and supplement the Federal Procurement Regulations. The regulations are prescribed under the authority of the Federal Property and Administrative Services Act of 1949, as amended.

Incremental Funding

This authority provides the Institute with the ability to write multiyear contracts with funding provided for specific phases or periods.

Negotiation

This term refers to the execution of purchases and contracts without formal advertising. Under negotiated contracts, the lowest offeror, with regard to cost, does not necessarily receive the award. Award is made on the basis of a proposal that offers the greatest advantage to the Government, with price and other factors considered. In R&D contracting, technical competence usually is the paramount consideration.

Negotiation Memorandum

This is a complete record of all actions leading to award of a contract. It records the history of the procurement and explains and supports the rationale, judgments, and authorities for all decisions and actions.

Principal Investigator/Project Director

A qualified individual designated by the contractor organization and approved by the Project Officer to direct the project or program being supported by the contract. This individual has primary responsibility for guiding and/or performing the work as described in the contract work statement. It should be noted that this individual is not the contractor but is an employee of the contractor.

Project Officer

The Government's technical representative responsible for monitoring the contractor's performance and adherence to the contract workscope. He also provides technical assistance to the contractor as required, and technical advice and interpretation to the contracting officer.

Project Plan

Results of planning by the project officer and the contracting officer are incorporated in the project plan. This also requests procurement action and is background material for the request for proposal.

Proposal Evaluation Criteria

Criteria against which technical proposals are evaluated. Offerors must be advised of the factors and their order of importance in the request for proposal.

Renewal

Supplemental agreement to an existing contract for continuation of work with a contractor. Usually, such extensions are for 6 months or longer.

Request for Proposal (RFP)

The Government's invitation to prospective offerors to submit a proposal based on the terms and conditions set forth in it.

BEST DOCUMENT AVAILABLE

Sources Sought

An attempt by the Government to determine if qualified sources are available to perform a specific requirement. Also used to determine the validity of certain noncompetitive procurements.

Technical Evaluation

Comparing a technical proposal against the requirements contained in the RFP and rating the proposal accordingly.

Unsolicited Proposal

A research and development proposal made to the Government without prior solicitation.

Work Statement (Scope of Work)

The document stating the technical objectives and requirements of a contract.